MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, September 24, 2020

Zoom Meeting

APPROVED MINUTES

I. Call to Order

Chairperson Madder called the meeting to order at 7:30 a.m.

A. Members Present:

Ryan Madder, MD, Chairperson – Spectrum Health
Kyle Sheiko, Vice-Chairperson – Michigan Outpatient Vascular Institute (MOVI)
Khaldoon Alaswad, MD, FACC, FSCAI – Henry Ford Health System (HFHS) (joined late)
Edouard Daher, MD – Eastlake Cardiovascular, PC
William R. Felten, MD, MSHAL, FACC
Carlos Fernandez, DO – Edward Sparrow Hospital (joined late)
Anita L. Hart, MD, FACP, SFHM – Blue Cross Blue Shield of Michigan
Srinivas Koneru, MD – K heart & Vascular Institute, PLLC
Mansoor A. Qureshi, MD – Trinity Health Michigan
Fadi A. Saab, MD – Advanced Cardiac & Vascular Centers for Amputation Prevention (joined late)
Frank Saltiel, MD, FACC, FSCAI – Ascension Michigan
Steven B. H. Timmis, MD FACC – HeartPointe Cardiology (Formerly Northpointe Heart Center)
Justin Trivax, MD – Beaumont Health (joined late)
Douglas J. Wunderly, MD – Bronson Healthcare Group/Advanced Cardiac Healthcare, PLC (joined late)

B. Members Absent:

Omar E. Ali, MD – Detroit Medical Center (DMC)
Susanne Mitchell – International Union, UAW
William S. Porter, RN – UAW Retiree Medical Benefits Trust

C. Michigan Department of Health and Human Services Staff present:

Tulika Bhattacharya
Marcus Connolly
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Mr. Sheiko, seconded by Dr. Qureshi to accept the agenda as presented. Motion carried.

IV. Review of Draft Minutes – August 27, 2020

Motion by Dr. Qureshi, seconded by Dr. Felten to accept the minutes as presented. Motion carried.

V. Charge 3 – Patent Foramen Ovale (PFO) Closures

Tom Forbes, MD, Children's Hospital of Michigan, provided a presentation. (Attachment A)

Discussion followed.

Motion by Dr. Madder, seconded by Mr. Saab to not allow PFO closures in facilities without open heart surgery. Motion carried.

VI. Charge 1 – Minimum Volume Requirements and Charge 2 – Exceptions for Rural Programs

Dr. Felten provided a presentation. (Attachment B)

Dr. Qureshi provided a presentation. (Attachment C)

Discussion followed.

Motion by Mr. Madder, seconded by Mr. Sheiko to leave existing volumes alone except for rural/micropolitan which will be discussed in second motion. Motion carried.

Motion by Dr. Felten, seconded by Mr. Sheiko to improve access for primary PCI in rural communities, change the maintenance guidelines for the current 500 procedure equivalents including 400 procedure equivalents to 250

procedure equivalents with 150 in diagnostic equivalents to initiate and maintain primary PCI. Motion carried.

VII. Next Steps

Charges 6 – 8 will be presented and discussed at the October meeting with electrophysiologists from Spectrum Health, Trinity Health, and possibly Beaumont Health.

The subcommittee for charges 4 and 5 consists of Dr. Madder, Dr. Timmis, Mr. Sheiko, Dr. Saab, Dr. Qureshi, Dr. Daher, Dr. Alaswad, and Dr. Trivax.

VIII. Future Meeting Dates

October 22, 2020; November 19, 2020; December 17, 2020; January 14, 2021; & February 18, 2021

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Saltiel, seconded by Mr. Daher to adjourn the meeting at 9:34 a.m. Motion carried.

Patent Foramen Ovale Closure-Can it be done without onsite surgical backup?

What is the Current Status as of 2020?

Thomas J Forbes, MD, FACC, FSCAI
Professor in Pediatrics-Wayne State University/Central Michigan University
Co-Director, Cardiac Catheterization Laboratory
Children's Hospital of Michigan
Co-director Great Lakes Structural Heart Center-Detroit Heart Hospital
Detroit Medical Center

Children's
HOSPITAL OF MICHIGAN

Attachment A

Disclosure

- Consultant and Proctor for Abbott Medical/Gore Medical/Biosence Webster Corp/Edwards Lifescience
- Consultant for Medtronic Corp/NuMed Medical/B Braun Medical
- DSMB for Harmony 25 Valve Medtronic
- Consultant for FDA Pediatric Device Division
- Trained over 500 physicians PFO/ASD Closure using ICE Worldwide

Attachment A

PFO CLOSURE TRENDS AND TECHNIQUES

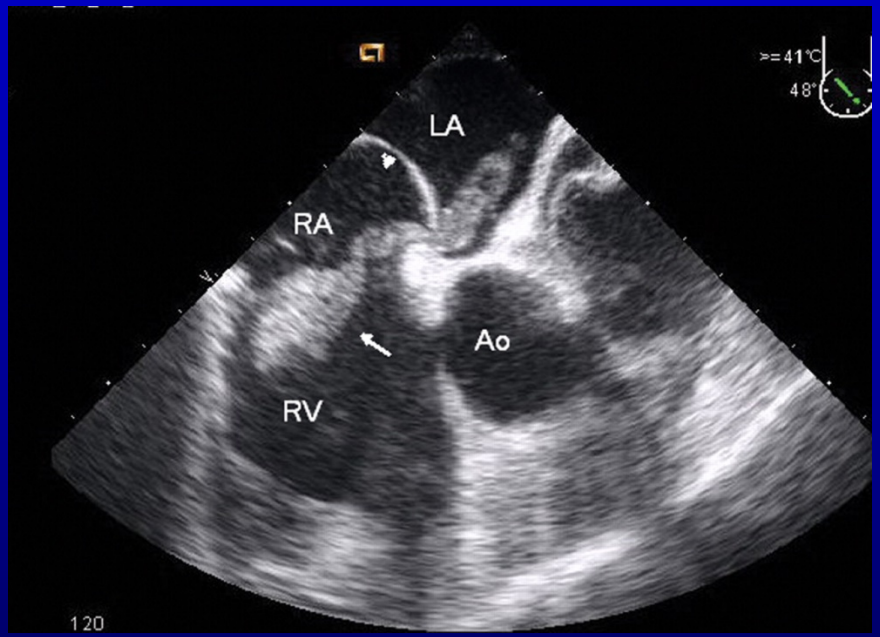
First Transcatheter PFO Closure was in Nov 1991

More common with newer devices in 2005

Exploded in 2017 due to support from randomized trials: RESPECT/REDUCE/CLOSE

Approximately 2-3,000 performed yearly in the US

99% performed in Hospital setting under moderate sedation with ICE imaging



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Respect Trial Design

- Design
  - → Multicenter: 69 Sites (62 US, 7 Canada)
  - → Prospective, 1:1 Randomized stratified by site and atrial septal aneurysm
  - → Device Group (Test):
    - Closure with the AMPLATZER™ PFO Occluder plus medical therapy
  - → Medical Group (Control): 5 Medical Treatment Regimens:
    - Aspirin
    - Coumadin
    - Clopidogrel
    - Aspirin with Dipyramidole
    - Aspirin with Clopidogrel (Dropped after 2006)
  - → Sample Size: Event-driven – continued enrollment until 25th endpoint
- Primary Analyses ---Four protocol-specified analyses with raw count primary analysis
- Trial Status ---Trial was conducted under an Investigational Device Exemption (IDE)

Sponsor St. Jude Medical, St. Paul, MN

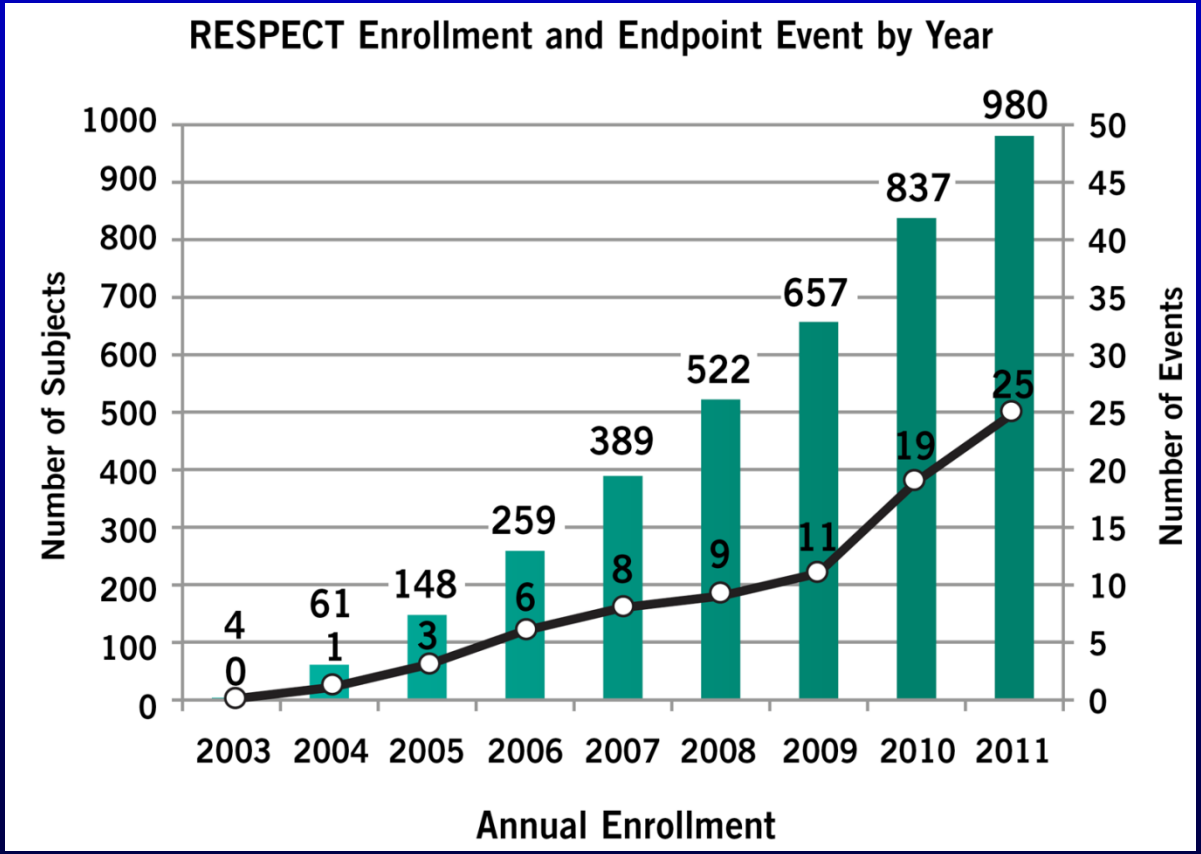
*Study initiated under AGA Medical, Plymouth, MN

Respect Trial

Results

All primary efficacy endpoints were recurrent ischemic strokes

No study related deaths



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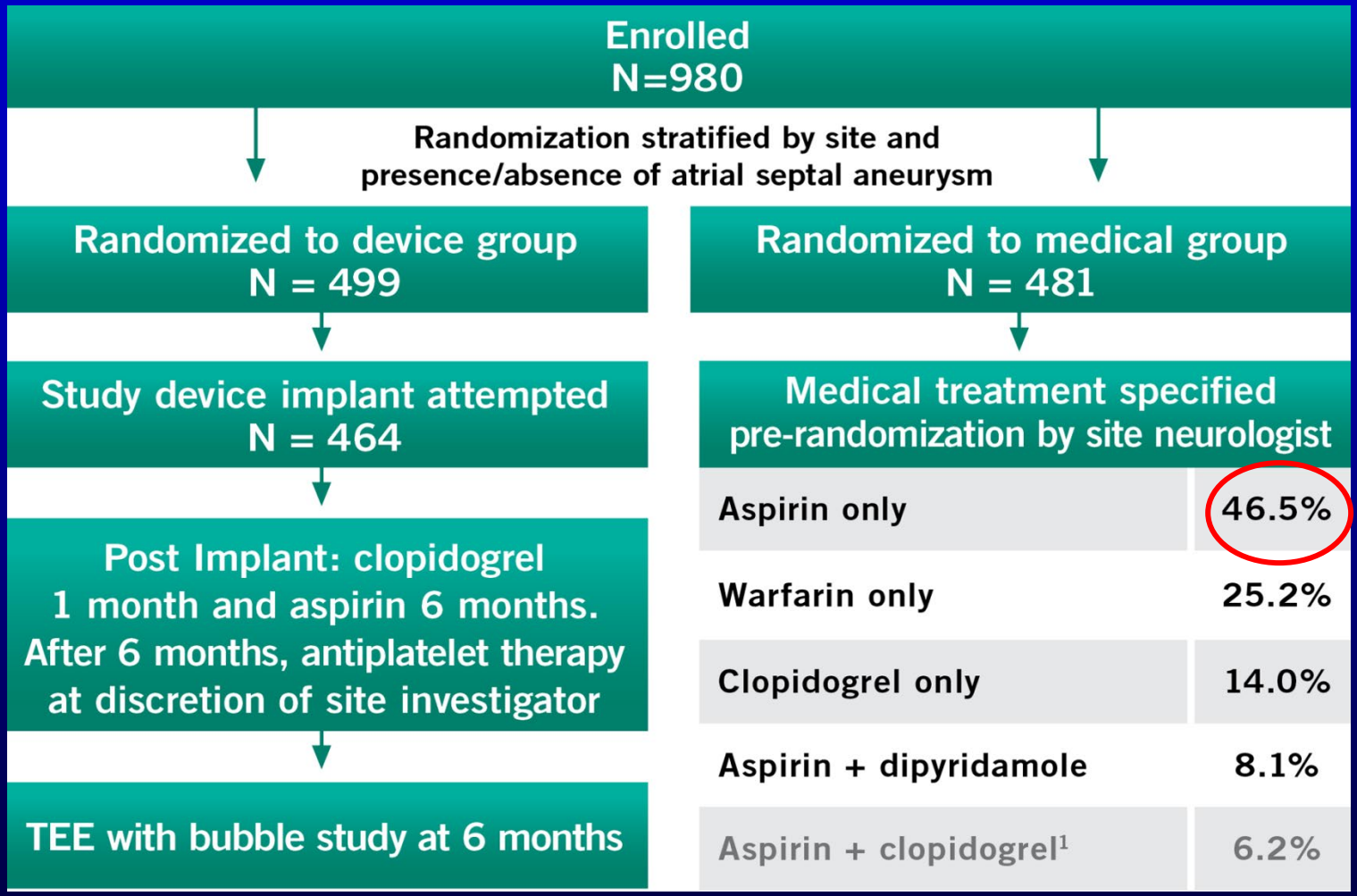
Respect Trial

Results



Attachment A

Respect Trial

Results

	Device Group[1] (N=499)	Medical Group[1] (N=481)	P-value[2]
Age (years)[3]	45.7 (9.7)	46.2 (10.0)	0.491
Gender male (%)	53.7	55.7	0.564
Days from qualifying stroke to randomization	130 (70)	130 (69)	0.891
Atrial septal aneurysm (%)	36.1	35.1	0.790
Maximal baseline shunt Grade II - III (%)[3,4] *(> 10 bubbles observed in LA)*	77.9	74.1	0.176
Qualifying Stroke Size			
Smaller infarct ≤ 1.5 cm	50.6	51.8	0.714
Larger infarct > 1.5 cm	49.4	48.2	

Respect Trial

Attachment A

Results

Serious Adverse Event Rates Related to Procedure, Device, or Study

Event	Device Group N=499 n (%)	Medical Group N=481 n (%)	P-value[7]
Thrombus on device	0 (0%)	N/A	N/A
Device embolization	0 (0%)	N/A	N/A
Atrial fibrillation[1]	3 (0.6%)	3 (0.6%)	1
Transient ischemic attack (TIA)	3 (0.6%)	3 (0.6%)	1
Major bleeding	8 (1.6%)	9 (1.9%)	0.810
Pericardial tamponade (procedure related)[2]	2 (0.4%)	N/A	N/A
Major vascular complications	4 (0.8%)	0 (0%)	0.124
Pulmonary embolism[3]	1 (0.2%)	0 (0%)	1
Cardiac thrombus[4]	2 (0.4%)	0 (0%)	0.500
Ischemic stroke[5]	2 (0.4%)	N/A	N/A
Death[6]	0 (0%)	0 (0%)	N/A

1.For all AE's, atrial fibrillation occurred in 3.0% versus 1.5% in the device and medical groups respectively, p=0.13
2.Pericardial tamponade is a subset of major bleeds, and thus counted in the major bleed category as well
3.For all SAEs, pulmonary embolism occurred in 1.2% and 0.2% in device and medical groups, respectively, p=0.124
4.1 case of right atrial thrombus resulted in abandonment of device implant procedure (no device received); 1 case of right atrial thrombus (located inferiorly) not attached to device detected in patient with DVT and PE 4 months after procedure
5.1 ischemic stroke one week post implant; 1 five months post implant with finding of severe shunting related to previously undiagnosed sinus venosus defect, requiring surgical closure
6.For all SAEs, there were 3 device group deaths (0.6%) and 6 medical group deaths (1.2%) all of which were not study related, p= 0.334

Attachment A

Respect Trial

Results-Device Performance

Procedural Outcomes	n/N (%)
Technical success[1]	460 / 464 (99.1%)
Procedural success[2]	444 / 462 (96.1%)
Effective closure[3]	244 / 261 (93.5%)

1. Defined as successful delivery and release of the device for subjects in whom the delivery system was introduced into the body
2. Defined as successful implantation with no reported in-hospital serious adverse events
3. Defined as complete obliteration or trivial residual shunting (Grade 0 or I at rest and Valsalva) at 6 months, adjudicated by echo core lab

Maximum Residual Shunting at Rest or Valsalva at 6 Months
Grade 0: 72.7%
Grade 1: 20.8%
Grade 2-3: 6.5%

Procedural & Device Related SAEs from RESPECT

Attachment A

- ***Procedural***-related
- N=467 through extended follow-up

Twelve (12) procedure-related SAEs occurred in 12 patients (2.4%)

Event	N (%)
Cardiac perforation (required repair)	**2 (0.4%)**
Cardiac perforation (No repair required)	**2 (0.4%)**
Access site bleeding	**3 (0.6%)**
Right atrial thrombus	**1 (0.2%)**
Deep vein thrombus	**1 (0.2%)**
Atrial fibrillation	**1 (0.2%)**
Other (drug allergy-vasovagal response)	**2 (0.4%)**

- ***Device***-related
- N=467 through extended follow -up

Thirteen (13) device-related SAEs occurred in 10 patients (2.0%)

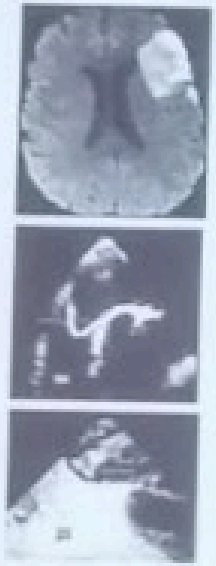
Event	N (%)
Ischemic stroke	**2 (0.4%)**
Pulmonary embolism	**2 (0.4%)**
Thrombus in the right atrium	**1 (0.2%)**
Explant	**2 (0.4%)**
Atrial fibrillation	**1 (0.2%)**
Residual shunt	**1 (0.2%)**
Other (chest tightness, atrial flutter, non-sustained ventricular tachycardia sepsis	**4 (0.8%)**

Procedure or Device Related SAEs

SAEs Adjudicated by DSMB

- No intra-procedure strokes
- No device embolization
- No device thrombosis
- No device erosion
- Very low rate of major vascular complications (0.9%) and device explants (0.4%)

Attachment A



CLOSE

Closure of Patent Foramen Ovale, Oral anticoagulants or Antiplatelet Therapy to Prevent Stroke Recurrence

The CLOSE investigators

Attachment A

CLOSE
Objectives and Methods

Objectives

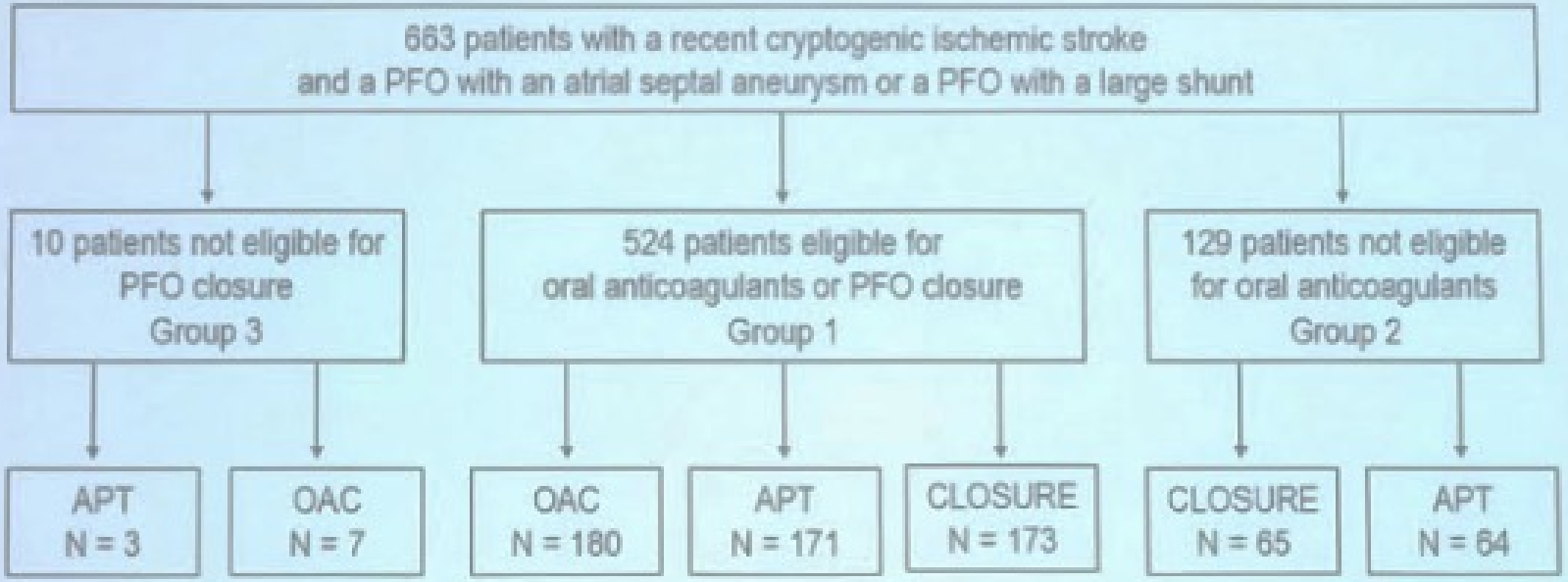
To assess whether **PFO closure with device plus antiplatelet therapy on one hand, and oral anticoagulants on the other hand, are superior to antiplatelet therapy** for secondary stroke prevention in patients 16 to 60 years old with cryptogenic stroke and PFO with atrial septal aneurysm or PFO with large shunt

Trial design

- Academic-driven, multicenter (32 sites in France and 2 sites in Germany), randomized, open-label, superiority trial with blinded adjudication of outcome events
- Funded by the French Ministry of Health
- 900 patients: 80% power to detect a 50% reduction in the rate of the primary outcome (3.5%/yr in the reference arm) in at least one experimental arm, 5-year study, α=5%
- 663 patients included from Dec. 2008 to Dec. 2014. Follow-up until Dec. 2016
- Mean follow-up 5.3 years

Attachment A

CLOSE
Flow diagram



APT = antiplatelet therapy OAC = oral anticoagulants CLOSURE = closure + antiplatelet therapy

Attachment A

CLOSURE versus ANTIPLATELET THERAPY

Secondary outcomes	CLOSURE (n = 238)	APT (n = 235)	HR (95%CI)
Ischemic stroke, TIA, or systemic embolism – no.	8	21	0.38 (0.16-0.81) P = 0.01
TIA – no.	8	8	0.98 (0.37-2.59)
Systemic embolism – no.	0	0	NA
Death – no.	0	0	NA
Effective PFO closure - no./total no. (%)	212/228 (93.0%)	-	NA

Safety outcomes	CLOSURE (n = 238)	APT (n = 235)	P value
Major procedural complications – no. (%)*	14 (5.9)	-	NA
Atrial fibrillation/flutter – no. (%)	11 (4.6)	2 (0.9)	0.02
Major bleeding complications – no. (%)	2 (0.89)	5 (2.1)	0.28

* atrial fibrillation (9), atrial flutter (1), supraventricular tachycardia (2), air embolism (1), and hyperthermia (1)

APT = antiplatelet therapy CLOSURE = closure + antiplatelet therapy

REDUCE Trial
Gore

- Supported the RESPECT Trial Results
  - → 2 Year Follow-up
  - → 664 Pts Enrolled (2:1 Device (441):Medical Tx (221))
  - → Noted 76.6% Reduction in Recurrent Stroke Events in the Device Group
  - → Pts underwent 2 year MRI study
    - Noted significant reduction of subclinical ischemic events in the Device Group
  - → Similar safety profile between devices
    - Atrial Fibrilation 6%
    - No perforation nor device embolization
    - Though acute perforations have occurred (1:1500 cases)

Conclusions

- I feel that the current data supports the ability of TRAINED physicians to close PFO's without onsite surgical backup
  - →Complication rates very low that may require acute surgical intervention (1:1500)
  - →Majority (90%) in more experienced centers are sent home same day with close (within a week) follow-up
- The important issue is that the physician needs to be experienced in the performance of closing PFO's and have adequate onsite echo available both during and after the procedure

Pictures of the year by NBC

Attachment B

Standard Advisory Committee (SAC) Meeting

- Review all minimum volume requirements for initiation, relocation, expansion and maintenance of cardiac catheterization services in Michigan
- Review increased exceptions for more rural programs where travel would cause increased risk for the patient.
- Recommend any necessary change to the Cardiac Catheterization Services CON Standards regarding the above

CON Commission cardiac catheterization services standard advisory committee meeting Thursday Sept. 24th, 2020
William Felten, MD, FACC

Priorities We Must Consider

- Cost
- Quality
- Access

Access to PCI

Attachment B

- Only 37% of all acute care adult hospitals in the US offer any PCI capability (Concannon et al. 2013)
- 84% of the US population lives within 60 minutes of a PCI-capable hospital however this still leaves 50 million residents living greater than 1 hour from the nearest PCI center
- Many new PCI services are opened in competitive markets, often with high private insurance penetration, where patients already have access to PCI
- Access to PCI is unevenly distributed among socioeconomic, racial/ethnic, and geographic (urban/rural) groups (Girotra and Cram 2012)
- The ACC and the AHA recommend that first medical contact-to-device times be no more than 120 minutes (O'Gara et al. 2013). Knowing that delays in transferring patients are often inevitable, certain communities with untimely access may need to create protocols and networks that are able to achieve the maximal benefit for their populations

CON Review Standards for Cardiac Cath Services: Sept. 2018

- Requirements to initiate cardiac catheterization services
  - An applicant hospital proposing to initiate a diagnostic cardiac cath service with a single lab in a rural or micropolitan area county shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac cath procedures based on data from the most recent 12-month period preceding the date the application was submitted to the department
  - In a metropolitan area: 750 procedure equivalents of which 300 in the category of diagnostic cardiac caths.
  - The numbers increase to 1000 procedure equivalents when two or more laboratories are proposed

Procedural equivalents defined on page 12 CON-210, approved 9/20/2018

CON Review Standards for Cardiac Cath Services: Dec. 2018

- Requirements to initiate primary or elective PCI services without on-site OHS services shall demonstrate the following:
  - The applicant hospital operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the department
  - The applicant hospital has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the department

Rural Michigan Counties	Attachment B
Alcona	Alger
Antrim	Arenac
Baraga	Charlevoix
Cheboygan	Clare
Crawford	Emmet
Gladwin	Gogebic
Huron	Iosco
Iron	Lake
Luce	Mackinac
Manistee	Montmorency
Newaygo	Oceana
Ogemaw	Ontonagon
Osceola	Oscoda
Ostego	Presque Isle
Roscommon Schoolcraft	Sanilac Tuscola

Attachment B

Micropolitan Michigan Counties	
Allegan	Alpena
Benzie	Branch
Chippewa	Delta
Dickinson	Grand Traverse
Gratiot	Ionia
Isabella	Hillsdale
Houghton	Kalkaska
Keweenaw	Leelanau
Lenawee	Marquette
Mason	Mecosta
Menominee	Missaukee
Shiawassee	St. Joseph
Wexford	

Current Micropolitan/Rural Cath Services in Michigan

- McLaren Central Michigan Mt Pleasant: 1 adult diagnostic cath lab
- McLaren Northern Michigan Petoskey: 3 adult diagnostic and therapeutic labs
- McLaren Thumb Region (Bad Axe): 1 adult diagnostic cath lab
- Munson Medical Center Traverse City: 7 adult diagnostic and therapeutic labs
- UP Health System Marquette: 4 adult diagnostic and therapeutic labs
- MidMichigan Health West Branch: 1 adult diagnostic lab
- MidMichigan Health Alpena: 1 adult diagnostic lab
- MidMichigan Health Alma: 1 adult diagnostic lab

Primary PCI Services in Rural/Micropolitan Areas

- There are currently no primary PCI services in a rural or micropolitan county in Michigan
- Only 4 primary and/or elective PCI programs exist outside of Southeast Michigan
  - Grand Rapids: 2
  - Holland: 1
  - Flint: 1

PCI Volume Benchmark History

- 1984: Operators with a cumulative experience of 50 cases had a success rate of 55% compared with 77% among operators with 150 cases.[1]
- 1993: The ACC/AHA guideline document recommended 75 PCIs as a minimum requirement for individual operators.[2]
- 1998: ACC's clinical competence statement on PCI recommended a minimum annual hospital PCI volume of 400 cases.[3]
- Initiatives such as the Leapfrog Group made 400 PCI the minimum requirement as part of their evidence-based volume referral standard for hospitals.[4]

Trends in the Performance of PCI

- Annual volume of PCI procedures peaked in 2006 and has since declined by over 30%
- Estimated that 61% of interventionalists perform < 40 Medicare fee-for-service PCIs annually[7]
- NCDR data show that 49% of facilities perform < 400 PCIs annually and 26% < 200 PCIs annually[8]
- Approximately 33% of facilities have no on-site surgery, and among these, 65% had an annual case volume of <200 PCI procedures

PCI Without On-Site Surgical Backup

- 2011 PCI Guideline: Elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery[9]
- Seven studies and 2 meta-analysis of primary PCI showed no difference for in-hospital or 30-day mortality between sites with and without on-site surgery[10]

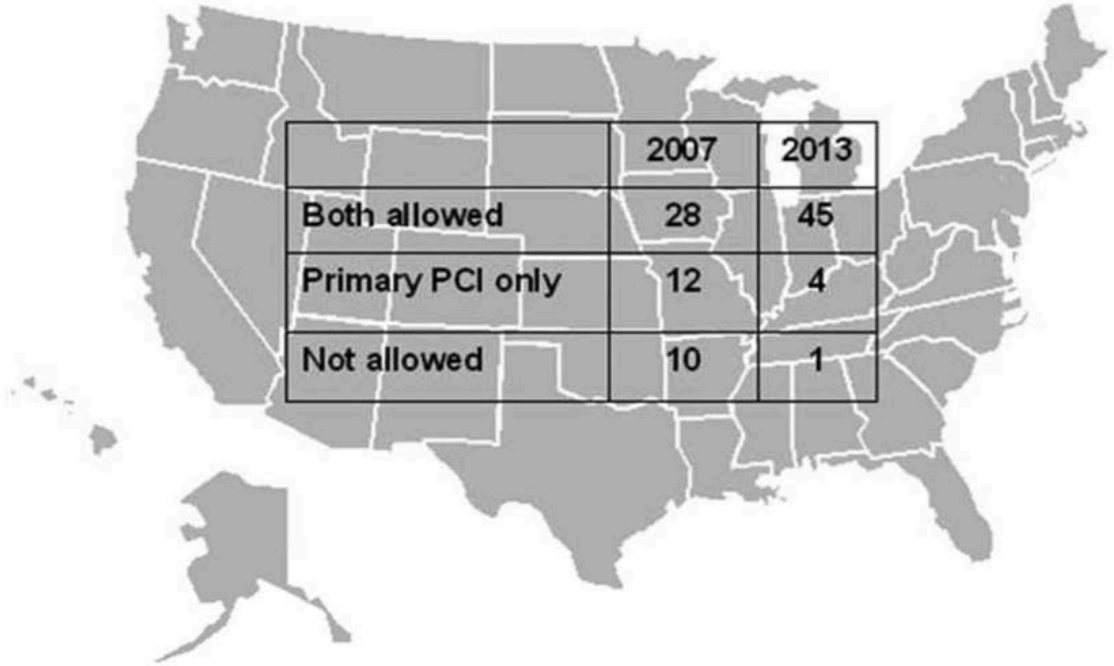


Figure 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

SCAI/ACC/AHA Expert Consensus Document: 2014 Update

Attachment B

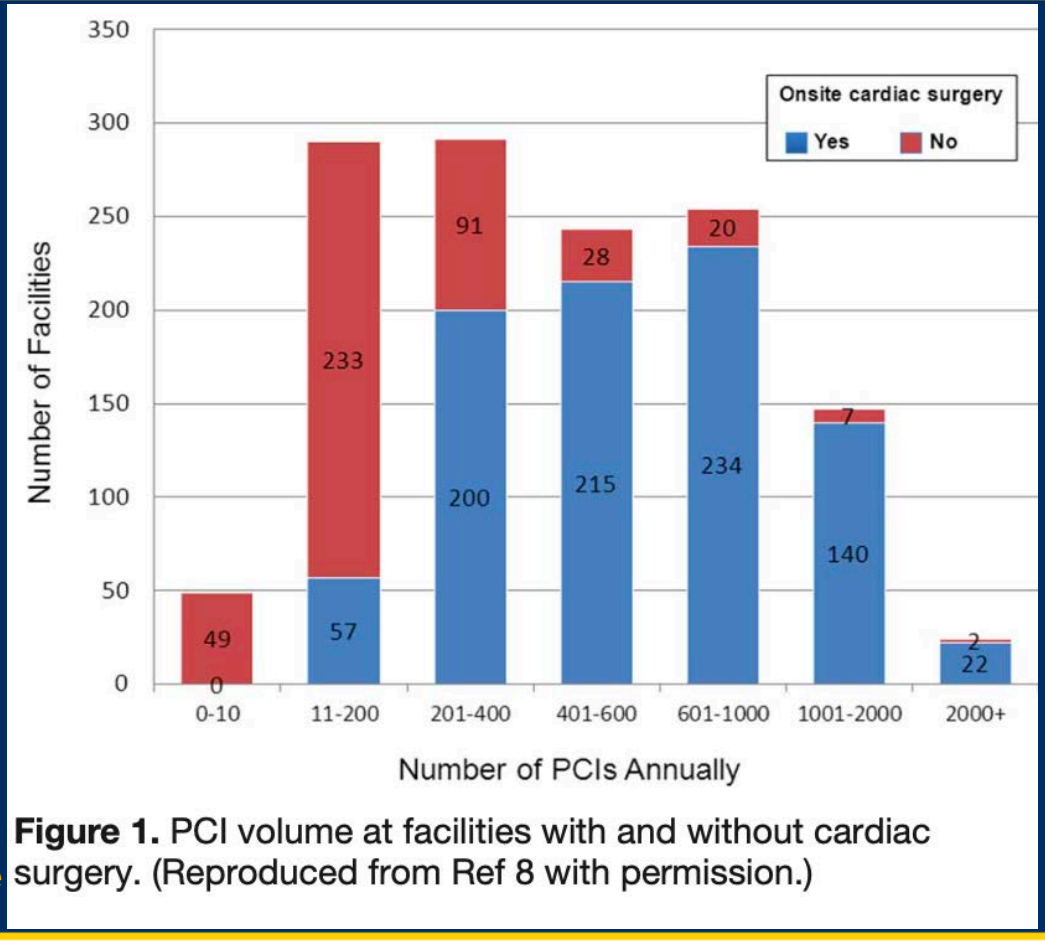


Figure 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref 8 with permission.)

SCAI/ACC/AHA Expert Consensus Document: 2014 Update

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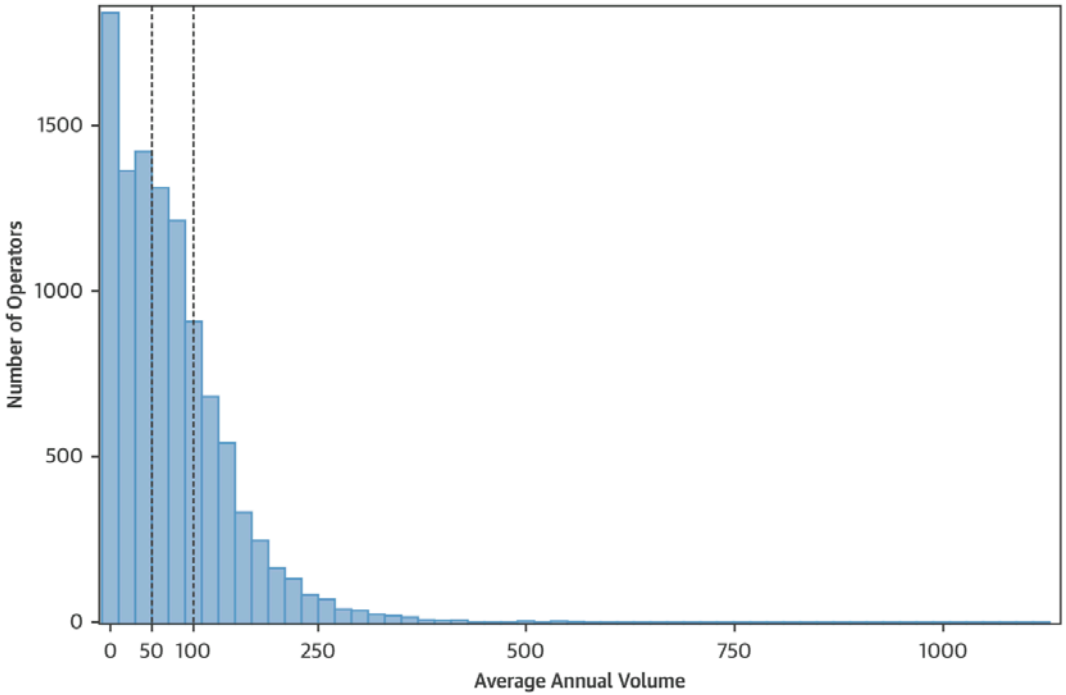
Current PCI Volume Recommendations: 2013

- The 2013 ACC/AHA/SCAI clinical competency statement reduced the recommended minimum number of PCI procedures performed annually be each operator from 75 to 50, averaged over 2 years.[5,6]
- Volume Definitions:
  - Low-volume: < 50 PCIs annually
  - Intermediate-volume: 50 to 100 PCIs annually
  - High-volume: > 100 PCIs annually
  - Extreme high-volume (97.5th percentile of the volume distribution): > 413 PCIs annually
  - Extreme low-volume (2.5th percentile): <26 PCIs annually

FIGURE 1 Distribution of Annual Operator Volumes



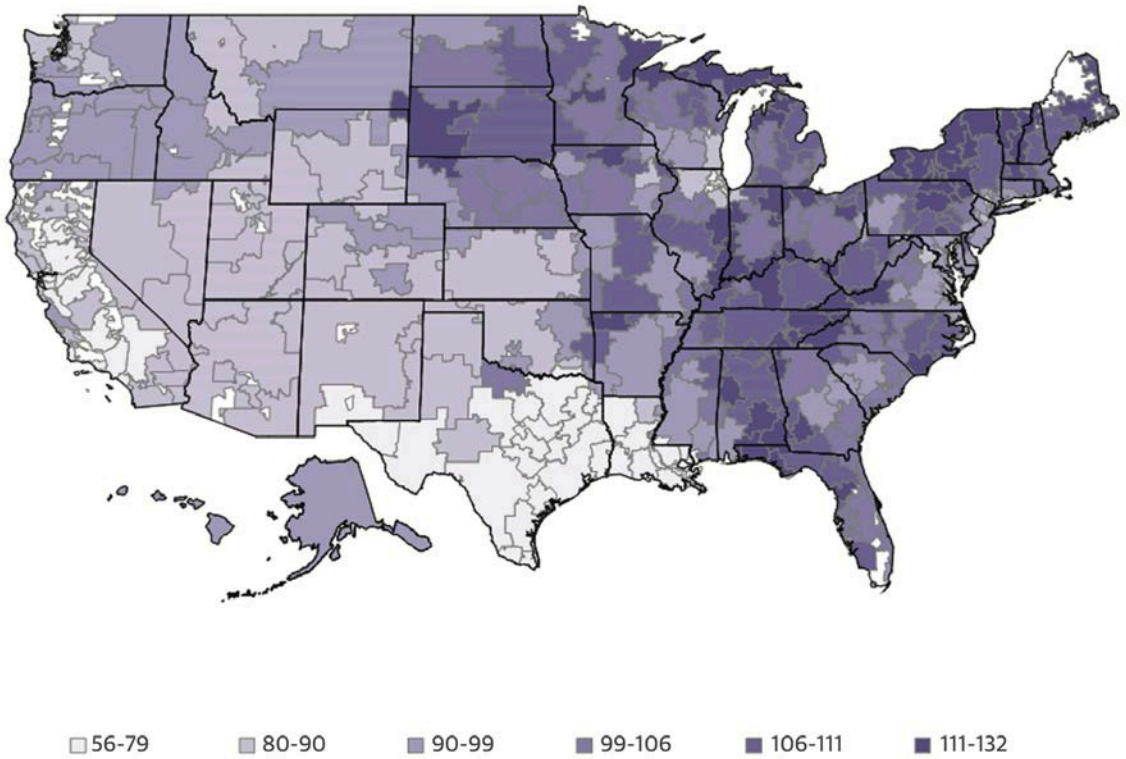
Operator volumes ranged from 1 to 1,121 percutaneous cardiovascular interventions (PCIs) per year; the median operator performed 59 PCIs per year. **Dashed lines** separate operators into low- (<50 PCIs per year; n = 4,628; 44%), intermediate- (50 to 100 PCIs per year; n = 3,001; 29%), and high- (>100 PCIs per year; n = 2,867; 27%) volume operators.

Outcomes of PCI in Relation to Procedural Characteristics and Operator Volumes: JACC 2017

Attachment B

Outcomes of PCI in Relation to Procedural Characteristics and Operator Volumes: JACC 2017

FIGURE 3 Median Annual Operator Volumes by Hospital Referral Region



Annual operator volumes varied by Dartmouth Health Atlas hospital referral region. In general, regions in the western and southwestern United States had the lowest median operator volumes (depicted in **lighter purple**); northeastern and midwestern regions had higher median operator volumes.

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Diagnostic Cardiac Cath & Operator Volume

Attachment B

- 3.5.1.1: Because of the low risk of diagnostic cardiac catheterization, it is difficult to arrive at any consensus as to what would constitute a minimum case load. There are no data supporting the prior recommendation of at least 150 diagnostic cases per year. Previously, this has been simply convention. The minimum laboratory diagnostic case load may vary widely depending on arbitrary requirements such as the presence of the CON process or state department of health regulations. It falls upon the director of the lab to ensure that all cardiac catheterization studies are appropriately indicated, performed and interpreted.
- A maximum # of procedures that an operator should be performing is also controversial, an area where there are essentially no data. This emphasizes the dependence on the QA process to monitor physician and laboratory behavior appropriately

Expert Consensus Document: JACC vol. 59, issue 24: June 2012

Are Volumes Still Important?

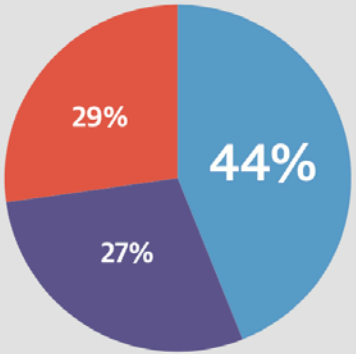
- There is persistence of the volume-outcome relationship, but as PCI has grown safer the absolute differences in outcomes have attenuated
- The relationship between operator volume and mortality was weakest in STEMI patients and strongest in patients with stable angina (JACC 2017. Review of the National Cardiovascular Data Registry 2009-2015)

CENTRAL ILLUSTRATION Procedure Characteristics and In-Hospital Outcomes by Operator Volume

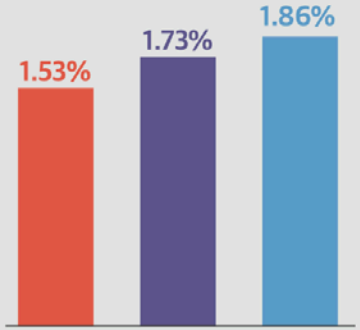
Percutaneous Coronary Intervention (PCI) operator procedure volumes, mortality rates, and characteristics

- High-volume operators: > 100 PCIs/year
- Intermediate-volume operators: 50–100 PCIs/year
- Low-volume operators: Under recommended minimum of 50 PCIs/year

Breakdown of operator groups



Mortality following PCI (%)



Characteristics of low-volume operators:

- Operated at lower volume hospitals
- More frequently performed emergency PCI and PCI for STEMI
- Less frequently used radial access
- Greatest volume of contrast dye; longest fluoroscopy times

Fanaroff, A.C. et al. J Am Coll Cardiol. 2017;69(24):2913–24.

Nearly one-half of all operators were low-volume operators (performed <50 percutaneous coronary interventions [PCI] per year). Compared with intermediate- (50 to 100 PCIs per year) and high-volume operators (>100 PCIs per year), low-volume operators worked at lower volume hospitals, performed more emergency PCIs and primary PCIs for ST-segment elevation myocardial infarction (STEMI), less frequently used radial access, and used more radiographic contrast dye and fluoroscopy minutes. Although in-hospital mortality was low (1.6% overall), it was higher for low- and intermediate-volume operators than for high-volume operators.

PCI Volume Benchmarks
JACC 2017

2013 ACCF/AHA/SCAI Update on Clinical Competence Statement

- This document reflects the overall decline in PCI volumes
  - Laboratories performing both primary and elective PCI, with and without on-site cardiac surgery should perform a minimum of 200 PCIs annually
  - Laboratories performing <200 cases annually must have stringent systems and process additional strategies protocols in place with close monitoring of clinical outcomes and that promote adequate operator and cath lab staff experience through collaborative relationships with larger volume facilities.
  - The existence of laboratories performing < 200 PCIs annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed.
  - Operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. These should be performed in institutions performing > 200 total and > 36 primary PCI procedures annually

Attachment B

FIGURE 1 Hypothetical Construct for a Comprehensive Evaluation of Operator PCI quality

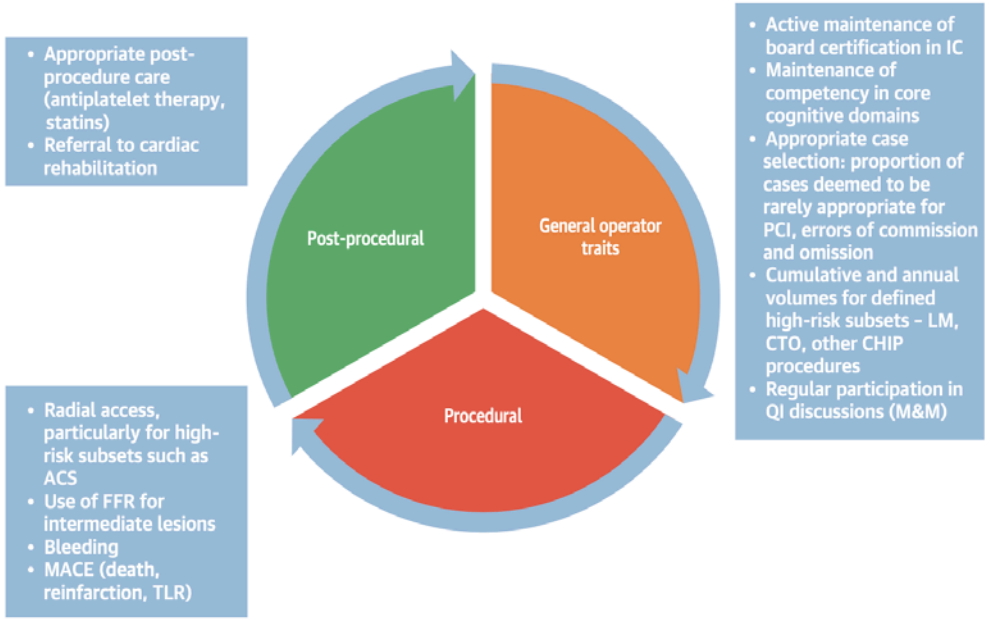


Figure demonstrates important components of a hypothetical comprehensive evaluation of operator PCI quality, including general operator traits and procedural and post-procedural aspects. ACS = acute coronary syndrome; CHIP = complex, high-risk, and indicated percutaneous coronary intervention; CTO = chronic total occlusion; FFR = fractional flow reserve; IC = interventional cardiology; LM = left main; M&M = mortality and morbidity; MACE = major adverse cardiac event(s); PCI = percutaneous coronary intervention; QI = quality improvement; TLR = target lesion revascularization.

JACC vol. 69, no. 24,2017

Access to Primary PCI

- An estimated 79% of US adults lived within a 1 hour drive of a PCI hospital, with a median driving tie of 11.3 min. (2000 US census and Amer. Hosp. Assoc. data)
- ~5 years later there was a 44% increase in the # of PCI facilities, however the # of adults within a 1 hour drive increased to only 79.9%.[11.] This mirrored the experience in Michigan where expansion of primary PCI to 12 hospitals without on-site surgery increased assess for only 4.8% of the population.[12]
- Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier study

Access to Primary PCI

- Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access.

- In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients

Summary Remarks

Attachment B

- We must keep in mind that in the current era, volume-outcome relationships are not as robust as in the past when POBA was the only treatment modality.
- Institutional volume thresholds of <200 PCIs annually and < 36 primary PCIs still appear to be consistently associated with worse outcomes.
- 26% of PCI facilities submitting data to the NCDR performed <200 total PCIs annually and 38% performed < 26 primary PCIs annually
- Although there is an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers.

Summary Remarks

- There was less evidence to support a threshold for individual operator volume for both elective and primary PCI
- The procedure volume must be sufficient to maintain proficiency in procedure performance interpretation (IAC Standards and Guidelines for Cardiovascular Catheterization Accreditation, 2018)
- Low-volume operators serve an important role by maintaining access to primary PCI for STEMI and performing a disproportionate number of emergency cases.
- The modest increase in the risk of in-hospital mortality, even among STEMI patients, treated by low-volume operators suggests that robust quality improvement processes are necessary to maintain access to primary PCI and improve outcomes

Summary Remarks

- Increase access to primary PCI for patients living in rural areas when transport time to a site performing PCI on-site is > 30 minutes (SCAI/ACC/AHA Expert Consensus Document, 2014)
- Individual operator volume is but one of several factors that should be considered in assessing operator competence.
  - Lifetime experience
  - Institutional volume
  - The operator's other cardiovascular interventions
  - Quality assessment of the operator's ongoing performance

CON Standards for Cardiac Catheterization
Proposed Revisions Related to Rural/Micropolitan Access

- Decrease maintenance volumes for an adult diagnostic cardiac cath service with 1 lab located in a rural or micropolitan county from 500 procedure equivalents with 300 in the category of cardiac to 250 procedure equivalents with 150 in the category of cardiac.
- Change the Primary PCI initiation requirements for historical cath volumes to be the same as the maintenance volumes

References

- [1]Kelsey SF, Mullin SM, Detre KM, et al. Effect of investigator experience on PTCA. AM J Cardiol 1984; 53: 56C-64C.
- [2]Ryan TJ. The critical question of procedure volume minimums for coronary angioplasty. JAMA 1995; 274: 1169-70
- [3]Hirshfeld JW Jr., Ellis SG, Faxon DP. Recommendations for the assessment and maintenance of proficiency in coronary interventional procedures: statement of the American College of Cardiology. J Am Coll Cardiol 1998; 31: 722-43.
- [4]Milstein A, Galvin RS, Delbanco SF, Salber P, Buck CR Jr. Improving the safety of health care: the leapfrog initiative. Eff Clin Pract 2000;3: 313-6.
- [5]Harold JG, Bass TA, Bashore TM et al. ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures. J Am Coll Cardiol 2013; 62: 357-96

References

- [6]Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention. J Am Coll Cardiol 2011;58: e44-122.
- [7]Maroney J, Khan S, Powell W, Klein LW. Current operator volumes of invasive coronary procedures in medicare patients: implications for future manpower needs I the catheterization laboratory. Catheter Cardiovasc Interv 201;81: 34-39
- [8]Dehmer GJ, Weaver D, Roe MT, Miliford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, Brindis RG. A contemporary view of diagnostic cardiac cath and percutanwous coronary intervention in the United States: a report from the CathPCI Registry of the National Cardiovascular Dfata Registry, 2010 through June 2011. J Am Coll Cardiol 2012;60:2017-2031.

References

- [9]Levine GN et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention. A report of the American College of Cardiology Foundation/ American Heart Association Task Force on practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation 2011;124:e574-e651
- [10]Singh M, Holmes DR Jr, Dehmer GJ, Lennon RJ, Wharton TP, Kutcher MA, Aversano T, Rihal CS. Percutaneous coronary intervention at centers with and without on-site surgery: a meta-analysis. JAMA 2011;306:2487-2494
- [11]Concannon TW, Nelson J, Goetz J, Griffith JL. A percutaneous coronary intervention lab in every hospital? Circ Cardiovasc Qual Outcomes 2012;5:14-20
- [12]Buckley JW, Bates ER, Nallamothu BK. Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in Michigan: a geographic information systems analysis. Am Heart J 2008;155:668-672
- [13]Horwitz JR, Nichols A, Nallamothu BK, Sasson C, Iwashyna TJ. Expansion of invasive cardiac services in the United States. Circulation 2013;128:803-810.

2018 Cardiac Catheterization CON Standards

SUMMARY OF VOLUME REQUIREMENTS

Mansoor Qureshi, MD
Sept. 24, 2020

CHARGE

Review all minimum volume requirements for:

- Initiation
- Relocation
- Expansion
- Maintenance

APPROACH TO THIS ANALYSIS

1. Definitions
2. Facility Requirements:
   - CON Requirements for facilities
   - Professional Guidelines for facilities
   - Comparison of CON to Professional Guidelines
3. Operator Requirements:
   - CON
   - Professional Guidelines for operators
   - Comparison of CON to Professional Guidelines

DEFINITIONS:

- *"Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory.*
- *"Cardiac catheterization session" means a continuous time period during which a patient may undergo one or more diagnostic or therapeutic cardiac or peripheral procedures in a cardiac catheterization laboratory.*
- *"Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory based on the type of procedures being performed. If a diagnostic and therapeutic procedure is performed in the same session, the higher procedure equivalent weighting will be used to evaluate utilization.*
  - *1 diagnostic session = 1.5 procedure equivalents*
  - *1 therapeutic session = 2.7 procedure equivalents*

Even higher equivalents for pediatrics, complex procedures

INITIATE – Diagnostic Service

"Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. A hospital that provides diagnostic cardiac catheterization services may also perform permanent pacemaker and ICD implantation (therapeutic procedures).

- Rural/Micropolitan (1 Lab) - Project **500** equivalents (300 equivalents must be from cardiac procedures)
- Metropolitan (1 Lab) - Project **750** equivalents (300 equivalents must be from cardiac procedures)
- Initiate with 2 or more Labs - Project **1,000** equivalents per lab (300 equivalents must be from cardiac procedures)

INITIATE – Primary PCI Service

"Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A hospital that provides primary PCI without on-site OHS may also perform right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.

- Hospital has performed: **500** procedure equivalents, of which 400 equivalents were from cardiac cath procedures in the most recent 12 months
- Hospital has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least **50** PCI sessions annually as the primary operator during the most recent 24-months
- Hospital projects it will perform: **36** primary PCI procedures per year

INITIATE – Elective PCI Service

"Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: … A hospital that provides elective PCI without on-site OHS may also perform right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.

- Hospital has performed: **500** procedure equivalents, of which 400 equivalents were cardiac cath procedures in the most recent 12 months
- Hospital has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least **50** PCI sessions annually as the primary operator during the most recent 24-months
- Hospital projects it will perform: **200** PCI procedures per year

INITIATE – Adult Therapeutic Service

"Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart.

"Therapeutic cardiac catheterization session" may include: PCI (elective, emergent), pericardiocentesis, permanent pacemaker implantation, ICD implantation (endovascular or subcutaneous), pacemaker or ICD generator change, pacemaker or ICD lead revision, cardiac ablation, and/or structural heart procedure. This also includes implantation of a circulatory support device such as IABP, Impella, ECMO or TandemHeart where this is the only therapeutic procedure. when PCI is performed in more than one coronary artery during the same setting, this is counted as one session.

- Hospital has performed: **300** adult diagnostic cardiac procedure equivalents in the most recent 12 months
- Hospital projects it will perform: **300** adult therapeutic cardiac procedure equivalents

INITIATE – Pediatric/Congenital Service

"Pediatric/congenital cardiac catheterization service" means providing cardiac and electrophysiology catheterization services on an organized, regular basis to infants and children ages 18 and below and patients born with congenital heart disease.

- Hospital projects it will perform: **600** equivalents in the category of pediatric/ congenital cardiac catheterizations

RELOCATE to a new site

- The existing hospital has performed:
  - **500** equivalents for a hospital in a rural or micropolitan county with one cath lab
  - **750** equivalents for a hospital in a metropolitan county with one cath lab
  - **1,000** equivalents per lab for a hospital with two or more cath labs
  - **300** equivalents in the category of adult diagnostic cardiac cath procedures
  - **300** equivalents in the category of adult therapeutic cardiac cath procedures
  - **600** equivalents in the category of pediatric/congenital cardiac cath procedures

EXPAND - add labs

- The existing hospital has performed:
  - **300** equivalents in the category of adult diagnostic cardiac cath procedures
  - **300** equivalents in the category of adult therapeutic cardiac cath procedures
  - **600** equivalents in the category of pediatric/congenital cardiac cath procedures
  - The hospital has performed **1,400** equivalents per existing and approved lab during the most recent 12-months

MAINTAIN – Ongoing Compliance

- Diagnostic: **300** equivalents in the category of adult diagnostic cardiac cath procedures
- Therapeutic: **300** equivalents in the category of adult therapeutic cardiac caths
- PPCI : **36** PPCI cases
- EPCI: **200** PCI procedures
- Pediatric/Congenital: **600** equivalents in the category of pediatric/congenital cardiac cath
- Rural/Micropolitan hospital with one cath lab: **500** equivalents
- Metropolitan hospital with one cath lab: **750** equivalents
- Hospital with 2 or more labs: **1,000** equivalents per lab

PROFESSIONAL GUIDELINES

Society for Cardiovascular Angiography and Intervention

- Primary PCI – "The performance of primary percutaneous coronary intervention (PPCI, PCI in the setting of acute ST elevation myocardial infarction) requires an additional cognitive and technical skill set [2]; therefore, it is recommended that that institutions should perform ≥36 PPCI/year, when possible."

- PCI – "Clinical competence guidelines state that in order to maintain proficiency while keeping complications at a low level, a minimum volume of ≥200 PCIs/year be achieved by all institutions "

SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory

PROFESSIONAL GUIDELINES

Accreditation for Cardiovascular Excellence

- Diagnostic – "Hospital-based diagnostic only laboratories and freestanding laboratories that do not perform coronary interventions must perform no less than 400 diagnostic coronary angiograms annually."
- Elective PCI – "Laboratories without on-site cardiac surgery must perform no less than 400 diagnostic coronary angiograms and 200 PCIs of which 36 PCIs are primary PCIs for acute myocardial infarction annually."
- Therapeutic - "Full-service laboratories should perform no less than 400 diagnostic coronary angiograms and 200 PCIs of which 36 PCIs are primary PCIs for acute myocardial infarction annually."

ACE Standards for Catheterization Laboratory Accreditation (2013)

FACILITY REQUIREMENTS COMPARISON

SERVICE TYPE	CON INITIATION REQUIREMENT	PROFESSIONAL GUIDELINE
Diagnostic – Rural/ Micropolitan	Project 500 equivalents of which 300 are dx cardiac	400 dx coronary angiograms
Diagnostic - Metropolitan	Project 750 equivalents of which 300 are dx cardiac	400 dx coronary angiograms
Diagnostic – 2+ labs	Project 1,000 equivalents per lab of which 300 are dx cardiac	400 dx coronary angiograms
Primary PCI	• Has performed 500 equivalents of which 400 are dx cardiac • Project 36 PPCI procedures	36 PPCI cases
Elective PCI	• Has performed 500 equivalents of which 400 are cardiac • Project 200 PCI procedures	200 PCI cases
Therapeutic	• Has performed 300 dx cardiac equivalents • Rpoject 300 tx cardiac equivalents	200 PCI cases
Pediatric/ Congenital	Project 600 pediatric/ congenital equivalents	Unknown

FACILITY REQUIREMENTS COMPARISON

SERVICE TYPE	CON ONGOING REQUIREMENT – Hospital has performed:	PROFESSIONAL GUIDELINE
Diagnostic	300 equivalents that are dx cardiac	400 dx coronary angiograms
Primary PCI	• 300 equivalents that are dx cardiac • 36 PPCI cases	36 PPCI cases
Elective PCI	• 300 equivalents that are dx cardiac • 300 equivalents that are tx cardiac • 200 adult PCI procedures	200 PCI cases
Therapeutic	• 300 equivalents that are dx cardiac • 300 equivalents that are tx cardiac	200 PCI cases
Pediatric/ Congenital	600 pediatric/ congenital equivalents	Unknown
Rural/Micro – 1 Lab	500 equivalents	N/A
Metro – 1 Lab	750 equivalents	N/A
Any - 2 or more labs	1,000 equivalents per lab	N/A

OPERATOR REQUIREMENTS

- CON volumes are based on SESSIONS, not procedures
- CON volumes may collectively be performed at multiple hospitals
- Operators credentialed to perform these shall average annually:
  - Diagnostic left-heart cath and/or coronary angiography: **50** diagnostic cardiac cath sessions
  - Therapeutic cardiac cath procedures, **50** adult therapeutic cardiac cath sessions
  - Pediatric/congenital cardiac cath, **50** pediatric /congenital cardiac cath sessions
  - Cath Lab Director, **100** caths per year for each of five preceding years

PROFESSIONAL GUIDELINES

Society for Cardiovascular Angiography and Intervention

- Diagnostic - "Because of the low risk of diagnostic cardiac catheterization, it is difficult to arrive at any consensus as to what would constitute a minimum caseload. There are no data supporting the prior recommendation of at least 150 diagnostic cases per year (1). …It falls upon the director of the laboratory to ensure that all cardiac catheterization studies are appropriately indicated, performed, and interpreted." [1]

- Primary PCI – "The performance of primary percutaneous coronary intervention (PPCI, PCI in the setting of acute ST elevation myocardial infarction) requires an additional cognitive and technical skill set [2]; therefore, it is recommended that operators perform 11 PPCI per year."[2]

- PCI – "Although the clinical competence guidelines acknowledge only a moderate correlation between operator percutaneous coronary interventions (PCI) volume and mortality, for each operator a minimum PCI volume of 50 per year is recommended, averaged over 2 years." [2]

1 - 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update
2 - SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory

PROFESSIONAL GUIDELINES

Society for Cardiovascular Angiography & Interventions

- "The director's qualifications should include at least 5 years of cardiac catheterization experience and possess recognized skill in the laboratory. …Directors that have not had time to accumulate 500 PCI cases should have a QA system in place…. This should be on a continuing basis until the minimum 500 PCI cases have been satisfactorily achieved and competence established." [1]

- "The director should be a licensed, board-certified interventional cardiologist, ideally with a minimum of 5 years' experience." [2]

1 - 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update
2 - SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory

OPERATOR REQUIREMENTS COMPARISON

ROLE	CON REQUIREMENT	PROFESSIONAL GUIDELINE
Diagnostic	50 diagnostic cardiac cath sessions	None
Primary PCI	None	11 PPCI cases
Therapeutic	50 therapeutic cardiac cath sessions	50 PCI cases
Pediatric/ Congenital	50 pediatric /congenital cardiac cath sessions	Unknown
Director	100 caths per year for each of five preceding years	• 500 PCI cases or QA • 5 years experience